

Pull 126

CLAIMS

1. A pharmaceutical composition suitable for oral administration in the form of a homogeneous solution which on exposure to water or gastrointestinal fluids forms an emulsion having a particle size of less than 5 microns, the solution comprising:
 - (b) a pharmaceutically effective amount of a cyclosporin,
 - (c) a carrier medium comprising a triglycerol monoester of a fatty acid having from 6 to 30 carbon atoms or mixtures thereof,
 - (d) polyethylene glycol,
 - (e) a non-ionic surfactant having a hydrophilic lipophilic balance (HLB) greater than 10, and
 - (f) optionally, a viscosity reducing agent,the composition being substantially free from ethanol.
2. A pharmaceutical composition according to Claim 1, wherein said fatty acid has 8 to 18 carbon atoms.
3. A pharmaceutical composition according to Claim 1, wherein the carrier medium comprises a triglycerol monoester of capric acid, caprylic acid, lauric acid, oleic acid, or a mixture thereof.
4. A pharmaceutical composition according to Claim 1, wherein the carrier medium comprises triglycerol monooleate.

5. A pharmaceutical composition according to Claim 1, wherein the cyclosporin is 1 to 25% by weight of the composition, the carrier medium is 15-50% by weight of the composition, the non-ionic surfactant is 5-40% by weight of the composition, the polyethylene glycol is 5 to 40% by weight of the composition, and the viscosity reducing agent, when present, is 5 to 25% by weight of the composition.
6. A pharmaceutical composition according to Claim 5 wherein the cyclosporin is 5 to 20% by weight of the composition, the carrier medium is 20-40% by weight of the composition, the non-ionic surfactant is 10-30% by weight of the composition, and the polyethylene glycol is 10 to 35% by weight of the composition.
7. A pharmaceutical composition according to Claim 6, wherein the cyclosporin is 10 to 20% by weight of the composition, the carrier medium is 25-35% by weight of the composition, the non-ionic surfactant is 15-25% by weight of the composition, the polyethylene glycol is 20 to 30% by weight of the composition, and the viscosity reducing agent, when present, is 10 to 20% by weight of the composition.
8. A pharmaceutical composition according to Claim 5, wherein the amount of cyclosporin is 5 to 400 mg, said fatty acid has 8 to 18 carbon atoms, the non-ionic surfactant has a HLB greater than 12, and the polyethylene glycol has a molecular weight of 200 to 1,000.
9. A pharmaceutical composition according to Claim 8, wherein the amount of cyclosporin is 20 to 200 mg, the non-ionic surfactant has a HLB greater than 14, and the polyethylene glycol has a molecular weight of 200 to 600.
10. A pharmaceutical composition according to Claim 8, wherein the non-ionic surfactant makes up from 15 to 25% by weight of the composition.

11. A composition according to Claim 1, wherein the polyethylene glycol has a molecular weight of from 200 to 1000.
12. A pharmaceutical composition according to Claim 1, wherein the non-ionic surfactant is selected from the group consisting of: polyoxyethylated hydrogenated vegetable oils, polyethoxylated castor oils, polyethoxylated hydrogenated castor oil, polyoxyethylene-sorbitan-fatty acid esters, and polyoxyethylene castor oil derivatives.
13. A pharmaceutical composition according to Claim 12, wherein the non-ionic surfactant is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, PEG-30 hydrogenated castor oil, PEG-40 hydrogenated castor oil, PEG-50 hydrogenated castor oil, PEG-60 hydrogenated castor oil, polyoxyethylene 40 castor oil, polyoxyethylene 60 castor oil, polyoxyethylene 35 castor oil, and mixtures thereof.
- 14
15. A pharmaceutical composition according to Claim 1, wherein the viscosity reducing agent is present and is selected from the group consisting of monoesters of glycerol and aliphatic monocarboxylic acids having from 6 to 30 carbon atoms, and mixtures thereof.
- 15
16. A pharmaceutical composition according to Claim ~~15~~ ¹⁴, wherein a viscosity reducing agent is present and selected from the group consisting of glycerol monocaprylate, glycerol monooleate, and mixtures thereof.
- 16
17. A pharmaceutical composition according to Claim 1, further comprising an antioxidant.

¹⁷
18. A composition according to claim 1, wherein the weight ratio of the carrier medium, non-ionic surfactant and viscosity reducing agent taken together to polyethylene glycol is greater than 1.

¹⁸
19. A pharmaceutical composition according to Claim ¹⁷18, wherein the cyclosporin is 1 to 25% by weight of the composition; the carrier medium is 15-50% by weight of the composition and comprises a triglycerol monoester of capric acid, caprylic acid, lauric acid, oleic acid, or a mixture thereof; the non-ionic surfactant is 5-40% by weight of the composition and is selected from the group consisting of: polyoxyethylated hydrogenated vegetable oils, polyethoxylated castor oils, polyethoxylated hydrogenated castor oil, polyoxyethylene-sorbitan-fatty acid esters, and polyoxyethylene castor oil derivatives; the polyethylene glycol is 5 to 40% by weight of the composition and has a molecular weight of 20 to 1,000; the viscosity reducing agent, when present, is 5 to 25% by weight of the composition and is selected from the group consisting of monoesters of glycerol and aliphatic monocarboxylic acids having from 6 to 30 carbon atoms, and mixtures thereof; and optionally, an antioxidant is in an amount of from 0.01% to 2% by weight of the total composition and is selected from the group consisting of BHA, BHT, and alpha-tocopherol.

¹⁹
20. A pharmaceutical composition according to Claim 1, wherein the cyclosporin is Cyclosporin A.

²⁰
21. A pharmaceutical composition according to Claim 1, formulated as a drinking solution.

²¹
22. A pharmaceutical composition according to Claim 1, formulated as a hard or soft capsule.

²²
23. A pharmaceutical composition according to Claim 1, contained within a soft gelatine capsule.